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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,547	12/13/2005	Shinji Tanaka	273504US0PCT	7194
22850	7590	03/19/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER KOSACK, JOSEPH R	
			ART UNIT	PAPER NUMBER
			1626	
			NOTIFICATION DATE	DELIVERY MODE
			03/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/540,547	Applicant(s) TANAKA ET AL.	
	Examiner Joseph R. Kosack	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/24/05 & 03/30/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-8 are pending in the instant application.

Priority

The claim to priority as a 371 filing of PCT/JP03/16258 filed December 18, 2003, which claims priority to JP 2002-374659 filed December 25, 2002 has been acknowledged in the instant application.

Information Disclosure Statement

The Information Disclosure Statements filed on June 24, 2005 and March 30, 2006 have been considered by the Examiner.

Claim Objections

Applicant is advised that should claim 4 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for where R3 and R4 are hydrogen, an alkyl group,

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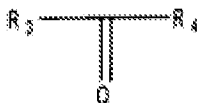
or a halogenated alkyl group, does not reasonably provide enablement for where R3 and R4 can be halogen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The Nature of the Invention

The nature of the invention is various processes to make compounds of Formulae I or II. The first process involves reacting the adamantyl alcohol with



and subsequently reacted with hydrogen halide gas to yield the compound of Formulae I or II. The second process involves reacting the adamantyl alcohol with DMSO and acetic anhydride, followed by reaction with sulfonyl chloride to yield the compound of Formulae I or II.

The State of the Prior Art and the Predictability or Lack Thereof in the Art

For the first process, the prior art has many examples of ketones and aldehydes which would allow one to practice the invention where R3 and R4 are hydrogen, an alkyl group, or a halogenated alkyl group. However, using an acid halide (when R3 or R4 is a halogen) would not form a hemiacetal which can then have the hydroxyl replaced by halogen, but would form an ester. See McMurry (*Organic Chemistry, Fourth Edition* 1996, pages 816-818).

For the second process, the prior art would predict that the only compound that would be formed by the process is where R3 and R4 are hydrogen and X is chlorine. See page 453 of Okada et al. (*Chem. Pharm. Bull.*, 1997, 452-456).

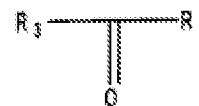
The Amount of Direction or Guidance Present and the Presence or Absence of Working

Examples

Two working examples are provided for the first process, but are only drawn to where R3 and R4 are hydrogen and X is chlorine. No working examples are provided for the second process.

The Breadth of the Claims

The breadth of the claims is various processes to make compounds of Formulae



I or II. The first process involves reacting the adamantyl alcohol with and subsequently reacted with hydrogen halide gas to yield the compound of Formulae I or II. The second process involves reacting the adamantyl alcohol with DMSO and acetic anhydride, followed by reaction with sulfonyl chloride to yield the compound of Formulae I or II.

The Quantity of Experimentation Needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine all of the reagents, reaction conditions and synthetic schemes in order to make and use the full scope of claimed compounds.

The Level of Skill in the Art

The level of skill in the art of organic synthesis and pharmaceuticals is high. However, due to the unpredictability in the art as described above, one of ordinary skill would be unable to make or use the claimed compound without undue experimentation in order to practice the invention as claimed.

Thus, the specification fails to provide sufficient support of the preparation and use of compounds of Formula I where R3 or R4 are halogen. As a result, the application would require one of skill to perform an exhaustive search and an inordinate number of experiments in order to make or use the claimed compound.

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 recites the limitation "by allowing two Y's to be put together." There is insufficient antecedent basis for this limitation in the claim. Therefore, claims 2, 5, and 7 are rejected as claims 5 and 7 depend off of claim 2.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims contain limitations such as “**having** 1 to 10 carbon atoms” (emphasis added). The limitation is indefinite as one would not know what the metes of bounds of the claim are. If there is a substituent that is 20 carbons long, would it be excluded by the claim as it has more than 10 carbon atoms or would it be embraced by the claims because it would still have 10 carbon atoms in it?

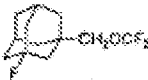
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ben-David et al. (*Journal of Fluorine Chemistry*, 1999, 75-78).

Ben-David et al. teach the compound  which reads on the compound of Formula I where n is 1, m is 1, Y is F, R1 and R2 are H, R3 and R4 are F, and X is F. See page 76.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (*Chem. Pharm. Bull.*, 1997, 452-456).

The instant claims are drawn to reacting a compound of either formula III or IV with dimethylsulfoxide in the presence of acetic anhydride to obtain a (methylthio)methyl ether compound and reacting it with sulfonyl chloride to obtain the compound of claim 1. Compounds where m and n are 0 are excluded, and the (methylthio)methyl ether compound may either be isolated or not isolated.

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Okada et al. teach the process of reacting an adamanyl alcohol with dimethylsulfoxide in the presence of acetic anhydride to obtain a (methylthio)methyl ether compound, isolating it, and reacting it with sulfonyl chloride to obtain a compound similar to that of claim 1. See page 453, Chart 1, steps 1 and 2 and page 455, column 1.

Okada et al. do not teach the reaction without isolation or where m and n are not 0.

Barring any secondary considerations, working with a crude reaction mixture is obvious over a reaction process with isolation as the components may be reacted with isolation occurring once the entire reaction scheme is accomplished. This is commonly done by those of ordinary skill in order to speed up production of compounds that have stable intermediates throughout the reaction scheme. Additionally, the compound of claim 1 where n is 1 would be a homologous structure to that of Okada et al. which has been held in the courts to be an obvious variant. Additionally, the reaction where n is not 0 would be expected to proceed in the same exact way as Okada et al. has set out with a reasonable expectation of success as there is no change in the functionality.

Conclusion

Claims 1-8 are rejected. Claim 8 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed, Ph.D./
Primary Examiner, Art Unit 1626

/Joseph R Kosack/
Examiner, Art Unit 1626